

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

MERZ NORTH AMERICA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 5:15-CV-262-H-KS
	)	
CYTOPHIL, INC., d/b/a REGENSCIENTIFIC,	)	
	)	
Defendant.	)	
<hr style="width: 40%; margin-left: 0;"/>	)	
CYTOPHIL, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 5:16-CV-745-H-KS
	)	
MERZ NORTH AMERICA, INC.,	)	
	)	
Defendant.	)	

**MEMORANDUM & RECOMMENDATION**

This matter is before the court on Cytophil’s Motion for Preliminary Injunction, filed in *Cytophil, Inc. v. Merz North America, Inc.*, No. 5:16-CV-745-H-KS, [DE #8], the motion having been referred to the undersigned by Senior United States District Judge Malcolm J. Howard for memorandum and recommendation pursuant to 28 U.S.C. § 636(b)(1)(B). The motion having been fully briefed, it is ripe for adjudication.

**BACKGROUND**

These consolidated actions involve U.S. Patent No. 6,537,574 (“the ‘574 Patent”) which is owned by Merz North America, Inc. (“Merz”). At issue in the litigation are two types of products that are injected into the human body to aid in soft-tissue augmentation or medialization. In Merz’s

Prolaryn Plus® and Radiesse® (Particle Suspension Products), Calcium Hydroxylapatite (CaHA) particles are suspended in a gel carrier solution. Prolaryn Gel® (a Gel Product) has a similar function but does not include any CaHA particles. Cytophil, Inc. (“Cytophil”) is a competitor of Merz and manufactures Renu® Voice and Renu® Gel. Renu® Voice is similar to Merz’s Particle Suspension Products and involves the use of CaHA particles. Renu® Gel, like Merz’s Prolaryn Gel®, is a Gel Product.

On June 18, 2015, Merz filed an action against Cytophil asserting it had infringed Merz’s ‘574 patent through the manufacture, marketing, and sale of Renu® Voice. *Merz North America, Inc. v. Cytophil*, No. 5:15-CV-262-H-KS (filed June 18, 2015) (“*Merz Action*”). Cytophil filed its answer on July 9, 2015, asserting various defenses and counterclaims against Merz. On September 4, 2015, Cytophil filed a motion, with Merz’s consent, requesting that it be allowed to withdraw its counterclaims for judgment declaring the ‘574 Patent unenforceable and for Sherman Act violations. The court granted Cytophil’s motion and dismissed the counterclaims by order entered September 10, 2015.

On February 4, 2016, Cytophil filed an action against Merz in the United States District Court for the Eastern District of Wisconsin. *Cytophil, Inc. v Merz North America, Inc.*, No. 2:16-CV-127-DEJ (E.D. Wis. filed Feb. 4, 2016). In that action, Cytophil asserted claims of false marking under the Patent Act, 35 U.S.C. § 292, and unfair competition under the Lanham Act, 15 U.S.C. § 1125(a). Cytophil alleged, *inter alia*, that Merz had marked its products with the ‘574 Patent knowing the products were not covered by the patent and in an effort to eliminate or decrease lawful competition. On March 31, 2016, and prior to any answer being filed, Cytophil filed a notice voluntarily dismissing the action.

On April 6, 2016, Cytophil filed another action against Merz in the United States District Court for the Eastern District of Wisconsin. *Cytophil, Inc. v Merz North America, Inc.*, No. 2:16-CV-423-LA (E.D. Wis. filed Apr. 6, 2016) (“*Cytophil Action*”). In its complaint, Cytophil asserted claims of false marking, Sherman Act violations, and commercial disparagement. That same day, Cytophil filed the motion presently before the court in which Cytophil seeks a preliminary injunction prohibiting Merz from (i) marking its products or their packaging with any reference to the ‘574 Patent; (ii) selling, offering to sell, shipping, distributing or publicly displaying any products marked with the ‘574 Patent; and (iii) advertising any of its products as covered by the ‘574 Patent.

With the consent of the parties, the *Cytophil Action* was transferred to this district on August 16, 2016, and restyled as *Cytophil, Inc. v Merz North America, Inc.*, No. 5:16-CV-745-H-KS (E.D.N.C.). Thereafter, the court consolidated the two actions.

### **DISCUSSION**

Injunctive relief at the preliminary stages of litigation is an extraordinary remedy that should be allowed only when such relief is necessary to protect the legal rights of the movant pending the litigation. *Micro Strategy, Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001). It is only where the movant makes a clear showing as to the following four factors that preliminary injunctive relief may issue: (1) reasonable likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3) the balance of hardships tipping in its favor; and (4) the issuance of an injunction is in the public interest. *Winter v. Natural. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The district court must then “balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief,” *Winter*, 555 U.S. at 24 (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987)),

“pay[ing] particular regard for the public consequences in employing the extraordinary remedy of injunction,” *id.* (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). Ultimately, though, the decision to grant or deny a preliminary injunction is left to the sound discretion of the district court. *Id.*

Cytophil contends that Merz has been unlawfully marking both its Gel Products and its Particle Suspension Products as protected by the ‘574 Patent when neither the products nor their use are covered by the patent. It seeks preliminary relief against Merz’s continued marking of the products as covered by the ‘574 Patent, as well as Merz’s sale, distribution or advertisement of products so marked. There appears to be no dispute that Merz’s Gel Product is not covered by the ‘574 Patent. (Merz’s Opp. Mot. Prelim. Injunction [DE #38] at 6 (“Merz N.A. does not contend that it uses the invention covered by the ‘574 Patent in its Gel Product.”).) However, resolution of Cytophil’s claim as to the Particle Suspension Products depends, in part, upon construction of the disputed claim terms of the ‘574 Patent— “rounded,” “substantially spherical,” and “substantially non-resorbable.”

Even assuming Cytophil has met its burden of showing a reasonable likelihood of success as to the false marking claim, it has not made a clear showing of irreparable harm so as to warrant the issuance of a preliminary injunction. In order to obtain preliminary injunctive relief, a movant “must make ‘a clear showing’ that it is at risk of irreparable harm.” *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (citing *Winter*, 555 U.S. at 22). This “entails showing ‘a likelihood of substantial and immediate irreparable injury.’” *Id.* (quoting *O’Shea v. Littleton*, 414 U.S. 488, 502 (1974)). A party’s delay in seeking injunctive relief is an important factor to be considered in determining the immediacy of any harm. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995).

In response to Cytophil’s motion, Merz has conceded that its Prolaryn Gel® is not covered by the ‘574 Patent and that the packaging for this product inadvertently referenced the ‘574 Patent until Cytophil brought this issue to Merz’s attention in December 2015. Merz states it has taken steps to correct the error, and the packaging no longer references the ‘574 Patent. In light of Merz’s representations concerning the discontinuance of any reference to the ‘574 Patent, the court concludes that Cytophil has not met its burden of demonstrating it will suffer irreparable harm absent the issuance of preliminary injunctive relief as to Merz’s Prolaryn Gel®.

With regard to Merz’s Particle Suspension Products, Prolaryn Plus® and Radiesse®, the court notes that the litigation between the parties began in June 2015, when Merz filed its suit claiming Cytophil’s infringement of the ‘574 Patent. Cytophil’s answer, filed July 9, 2015, included affirmative defenses and counterclaims in which it was averred that Merz’s products are not covered by the ‘574 Patent. In December 2015, Cytophil apparently discussed with Merz the reasons for its belief that Merz was engaged in false patent marking. (*See Cytophil Action Decl. Eric V.C Jansson* [DE #11] ¶¶ 26-27). Cytophil again raised the issue in February 2016 in its first suit against Merz for false marking in the United States District Court for the Eastern District of Wisconsin. Additionally, Cytophil’s complaint against Merz, filed in the action pending before this court, suggests that Cytophil has known for “years” of the alleged false marking by Merz. (*See, e.g., Cytophil Action Compl.* [DE #1] ¶ 35 (“Both Cytophil and Merz are fully aware, and have been aware for years, of the scope limitations of the ‘574 Patent . . .”).)

Notwithstanding Cytophil’s knowledge of Merz’s actions in marking its products as covered by the ‘574 Patent, as well as the pendency of litigation between the parties, Cytophil did not seek injunctive relief against Merz until April 6, 2016. This period of delay – “years” according

to Cytophil – strongly suggests there is no urgency to Cytophil’s request and, therefore, militates against a preliminary injunction. *See High Tech.*, 49 F.3d at 1557.

Given the above considerations, the history and procedural posture of this case, and the substantial dispute between the parties concerning the ‘574 Patent’s claim terms, the undersigned recommends that the court deny Cytophil’s request for a preliminary injunction.

### **CONCLUSION**

For the foregoing reasons, it is RECOMMENDED that Cytophil’s motion for preliminary injunction [DE #8] be DENIED.

IT IS DIRECTED that a copy of this Memorandum and Recommendation be served on each of the parties or, if represented, their counsel. Each party shall have until **March 9, 2017**, to file written objections to the Memorandum and Recommendation. The presiding district judge must conduct his or her own review (that is, make a de novo determination) of those portions of the Memorandum and Recommendation to which objection is properly made and may accept, reject, or modify the determinations in the Memorandum and Recommendation; receive further evidence; or return the matter to the magistrate judge with instructions. *See, e.g.*, 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3); Local Civ. R. 1.1 (permitting modification of deadlines specified in local rules), 72.4(b), E.D.N.C.

A party that does not file written objections to the Memorandum and Recommendation by the foregoing deadline, will be giving up the right to review of the Memorandum and Recommendation by the presiding district judge as described above, and the presiding district judge may enter an order or judgment based on the Memorandum and Recommendation without such review. In addition, a party's failure to file written objections by the foregoing deadline may bar the party from appealing to the Court of Appeals from an order or judgment of the presiding

district judge based on the Memorandum and Recommendation. *See Wright v. Collins*, 766 F.2d 841, 846-47 (4th Cir. 1985).

This 23rd day of February 2017.

  
KIMBERLY A. SWANK  
United States Magistrate Judge